

Office of Healthcare Inspections

Report No. 13-00026-197

Community Based Outpatient Clinic Reviews at VA Maine Healthcare System Augusta, ME

May 16, 2013

Washington, DC 20420

Why We Did This Review

The VA OIG is undertaking a systematic review of VHA's CBOCs to assess whether CBOCs are operated in a manner that provides veterans with consistent, safe, high-quality health care.

The Veterans' Health Care Eligibility Reform Act of 1996 was enacted to equip VA with ways to provide veterans with medically needed care in a more equitable and cost-effective manner. As a result, VHA expanded the Ambulatory and Primary Care Services to include CBOCs located throughout the United States. CBOCs were established to provide more convenient access to care for currently enrolled users and to improve access opportunities within existing resources for eligible veterans not currently served.

Veterans are required to receive one standard of care at all VHA health care facilities. Care at CBOCs needs to be consistent, safe, and of high quality, regardless of model (VA-staffed or contract). CBOCs are expected to comply with all relevant VA policies and procedures, including those related to quality, patient safety, and performance.

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Glossary

C&P credentialing and privileging

CBOC community based outpatient clinic

CDC Centers for Disease Control and Prevention

EHR electronic health record

EKG electrocardiogram

EOC environment of care

FPPE Focused Professional Practice Evaluation

FY fiscal year

HCS Healthcare System

IT Information Technology

MH Mental Health

NCP National Center for Health Promotion and

Disease Prevention

NC noncompliant

OI&T Office of Information and Technology

PII Personally Identifiable Information

OIG Office of Inspector General
VHA Veterans Health Administration

VISN Veterans Integrated Service Network

WH women's health

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Executive Summary

Purpose: We evaluated select activities to assess whether the CBOCs operated in a manner that provides veterans with consistent, safe, high-quality health care.

We conducted an onsite inspection of the CBOCs during the week of March 11, 2013.

The review covered the following topic areas:

- WH
- Vaccinations
- C&P
- EOC
- Emergency Management

For the WH and vaccinations topics, EHR reviews were performed for patients who were randomly selected from all CBOCs assigned to the parent facility. The C&P, EOC, and emergency management onsite inspections were only conducted at the randomly selected CBOCs (see Table 1).

VISN	Facility	CBOC Name	Location	
	VA Maine HCS	Bangor	Bangor, ME	
1		Calais	Calais, ME	
Table 1. Sites Inspected				

Review Results:

We made recommendations in two review areas.

Recommendations: The VISN and Facility Directors, in conjunction with the respective CBOC managers, should take appropriate actions to:

- Ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the allotted timeframe and that notification is documented in the EHR.
- Ensure that patients with normal cervical cancer screening results are notified of results within the defined timeframe and that notification is documented in the EHR.
- Ensure that patients' PII is protected and secured at the Bangor CBOC.

- Ensure that the Chief of OI&T evaluates security of the IT closet and implements required measures at the Bangor CBOC.
- Ensure that all identified EOC deficiencies and corrective actions at the Bangor and Calais CBOCs are tracked and trended by the EOC Committee.

Comments

The VISN and Facility Directors agreed with the CBOC review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 11–14, for the full text of the Directors' comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D. Assistant Inspector General for Healthcare Inspections

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Objectives and Scope

Objectives

- Evaluate whether CBOCs comply with selected VHA requirements regarding the provision of cervical cancer screening, results reporting, and WH liaisons.
- Evaluate whether CBOCs properly provided selected vaccinations to veterans according to CDC guidelines and VHA recommendations.
- Determine whether CBOC providers are appropriately credentialed and privileged in accordance with VHA Handbook 1100.19.1
- Determine whether CBOCs are in compliance with standards of operations according to VHA policy in the areas of environmental safety and emergency planning.

Scope and Methodology

Scope

We reviewed selected clinical and administrative activities to evaluate compliance with requirements related to patient care quality and the EOC. In performing the reviews, we assessed clinical and administrative records as well as completed onsite inspections at randomly selected sites. Additionally, we interviewed managers and employees. The review covered the following five activities:

- WH
- Vaccinations
- C&P
- EOC
- **Emergency Management**

Methodology

To evaluate the quality of care provided to veterans at CBOCs, we conducted EHR reviews for the WH and vaccinations topic areas. For WH, the EHR reviews consisted of a random sample of 50 women veterans (23-64 years of age). For vaccinations, the EHR reviews consisted of random samples of 75 veterans (65 and older) and 75 additional veterans (all ages), unless fewer patients were available, for

¹ VHA Handbook 1100.19, Credentialing and Privileging, November 14, 2008.

² VHA Handbook 1006.1, Planning and Activating Community-Based Outpatient Clinics, May 19, 2004.

pneumococcal and tetanus, respectively. The study populations consisted of patients from all CBOCs assigned to the parent facility.³

The C&P, EOC, and emergency management onsite inspections were only conducted at the randomly selected CBOCs. Two CBOCs were randomly selected from the 56 sampled parent facilities, with sampling probabilities proportional to the numbers of CBOCs eligible to be inspected within each of the parent facilities.⁴

In this report, we make recommendations for improvement. Recommendations pertain to issues that are significant enough to be monitored by the OIG until corrective actions are implemented.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

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³ Includes all CBOCs in operation before October 1, 2011.

⁴ Includes 96 CBOCs in operation before October 1, 2011, that had 500 or more unique enrollees.

CBOC Profiles

To evaluate the quality of care provided to veterans at CBOCs, we designed reviews with an EHR component to capture data for patients enrolled at all of the CBOCs under the parent facility's oversight.⁵ The table below provides information relative to each of the CBOCs under the oversight of the parent facility.

				Uniques FY	Visits FY	
VISN	Parent Facility	CBOC Name	Locality ⁶	2012 ⁷	2012 ⁷	CBOC Size ⁸
		Aroostook County (Caribou) (Caribou, ME)	Rural	2,740	13,025	Mid-Size
		Bangor (Bangor, ME)	Urban	8,312	50,088	Large
		Calais (Calais, ME)	Rural	1,067	3,905	Small
1	VA Maine HCS	Lewiston-Auburn Area (Lewiston, ME)	Rural	2,482	6,105	Mid-Size
		Portland (Portland, ME)	Urban	3,391	18,117	Mid-Size
		Rumford (Rumford, ME)	Rural	1,883	7,410	Mid-Size
		Saco (Saco, ME)	Rural	4,920	20,724	Mid-Size
	Table 2. Profiles					

⁵ Includes all CBOCs in operation before October 1, 2011.

⁶ http://vaww.pssg.med.va.gov/

http://vssc.med.va.gov

⁸ Based on the number of unique patients seen as defined by VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, the size of the CBOC facility is categorized as very large (> 10,000), large (5,000-10,000), mid-size (1,500-5,000), or small (< 1,500).

WH and Vaccination EHR Reviews Results and Recommendations

WH

Cervical cancer is the second most common cancer in women worldwide.⁹ Each year, approximately 12,000 women in the United States are diagnosed with cervical cancer.¹⁰ The first step of care is screening women for cervical cancer with the Papanicolaou test or "Pap" test. With timely screening, diagnosis, notification, and treatment, the cancer is highly preventable and associated with long survival and good quality of life.

VHA policy outlines specific requirements that must be met by facilities that provide services for women veterans. We reviewed EHRs, meeting minutes and other relevant documents, and interviewed key WH employees. Table 3 shows the areas reviewed for this topic. The review elements marked as noncompliant needed improvement.

NC	Areas Reviewed		
	Cervical cancer screening results were entered into the		
	patient's EHR.		
X	The ordering VHA provider or surrogate was notified of results		
	within the defined timeframe.		
X	Patients were notified of results within the defined timeframe.		
	Each CBOC has an appointed WH Liaison.		
	There is evidence that the CBOC has processes in place to		
	ensure that WH care needs are addressed.		
Table 3. WH			

There were 20 patients who received cervical cancer screening at the VA Maine HCS' CBOCs.

<u>Provider Notification</u>. VHA requires that normal cervical cancer screening results must be reported to the ordering provider or surrogate within 30 calendar days of the report being issued and the notification is documented in the EHR.¹² We reviewed the EHRs of 17 patients who had normal cervical cancer screening results and did not find documentation in 4 records that the ordering provider or surrogate was notified within 30 calendar days.

⁹ World Health Organization. *Cancer of the cervix*. Retrieved from: http://www.who.int/reproductivehealth/topics/cancers/en/index.html.

¹⁰ U.S. Cancer Statistics Working Group, United States Cancer Statistics: 1999–2008 Incidence and Mortality Webbased report.

¹¹ VHA Handbook 1330.01, Health Care Services for Women Veterans, May 21, 2010.

¹² VHA Handbook 1330.01.

<u>Patient Notification of Normal Cervical Cancer Screening Results.</u> We reviewed 17 EHRs of patients who had normal cervical cancer screening results and determined that 6 patients were not notified within the required 14 days from the date the pathology report became available.

Recommendations

- 1. We recommended that a process be established to ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the allotted timeframe and that notification is documented in the EHR.
- 2. We recommended that managers ensure that patients with normal cervical cancer screening results are notified of results within the defined timeframe and that notification is documented in the EHR.

Vaccinations

The VHA NCP was established in 1995. The NCP establishes and monitors the clinical preventive services offered to veterans, which includes the administration of vaccinations.¹³ The NCP provides best practices guidance on the administration of vaccinations for veterans. The CDC states that although vaccine-preventable disease levels are at or near record lows, many adults are under-immunized, missing opportunities to protect themselves against diseases such as tetanus and pneumococcal infections.

Adults should receive a tetanus vaccine every 10 years. At the age of 65, individuals who have never had a pneumococcal vaccination should receive one. For individuals 65 and older who have received a prior pneumococcal vaccination, one-time revaccination is recommended if they were vaccinated 5 or more years previously and were less than 65 years of age at the time of the first vaccination.

We reviewed documentation of selected vaccine administrations and interviewed key personnel. Table 4 shows the areas reviewed for this topic.

NC	Areas Reviewed		
	Staff screened patients for the tetanus vaccination.		
	Staff administered the tetanus vaccination when indicated.		
	Staff screened patients for the pneumococcal vaccination.		
	Staff administered the pneumococcal vaccination when indicated.		
	Staff properly documented vaccine administration.		
	Managers developed a prioritization plan for the potential occurrence o		
	vaccine shortages.		
Table 4. Vaccinations			

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¹³ VHA Handbook 1120.05, Coordination and Development of Clinical Preventive Services, October 13, 2009.

<u>Documentation of Vaccinations</u>. Federal Law requires that documentation for administered vaccinations include specific elements, such as the vaccine manufacturer and lot number of the vaccine used. We reviewed the EHRs of 32 patients who were administered a pneumococcal vaccine at the parent facility or its associated CBOCs. We did not find documentation of all the required information related to pneumococcal vaccine administration in 18 of the EHRs when the vaccine was given before 2007. However, in 2007, a template recommended by the VISN was introduced at the facility to correct the documentation. Generally, records of vaccines received after 2007 contained all required elements. We made no recommendations.

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¹⁴ Childhood Vaccine Injury Act of 1986 (PL 99 660) sub part C, November 16, 2010.

Onsite Reviews Results and Recommendations

CBOC Characteristics

We formulated a list of CBOC characteristics that includes identifiers and descriptive information for the randomly selected CBOCs (see Table 5).

	Bangor	Calais
VISN	1	1
Parent Facility	VA Maine HCS	VA Maine HCS
Types of Providers	Licensed Clinical Social Worker Licensed Professional Counselor Nurse Practitioner Physician Assistant Primary Care Physician Psychiatrist Psychologist	Licensed Clinical Social Worker Primary Care Physician
Number of MH Uniques, FY 2012	1,847	223
Number of MH Visits, FY 2012	15,095	877
MH Services Onsite	Yes	Yes
Specialty Care Services Onsite	Audiology Cardiology Dental Optometry WH	None
Ancillary Services Provided Onsite	EKG Laboratory Pharmacy Physical Medicine Radiology	None
Tele-Health Services	EKG MH MOVE ¹⁵ Retinal Imaging	EKG MH Primary Care Retinal Imaging
	Table 5. Characteristics	

¹⁵ VHA Handbook 1120.01, MOVE! Weight Management Program for Veterans, March 31, 2011.

C&P

We reviewed C&P folders, scopes of practice, meeting minutes, and VetPro information and interviewed senior managers to determine whether facilities had consistent processes to ensure that providers complied with applicable requirements as defined by VHA policy. Table 6 shows the areas reviewed for this topic.

NC	Areas Reviewed			
Each provider's license was unrestricted.				
New Provider				
	Efforts were made to obtain verification of clinical privileges			
	currently or most recently held at other institutions.			
	FPPE was initiated.			
	Timeframe for the FPPE was clearly documented.			
	The FPPE outlined the criteria monitored.			
	The FPPE was implemented on first clinical start day.			
	The FPPE results were reported to the medical staff's Executive			
	Committee.			
	Additional New Privilege			
	Prior to the start of a new privilege, criteria for the FPPE were			
	developed.			
	There was evidence that the provider was educated about FPPE			
	prior to its initiation.			
	FPPE results were reported to the medical staff's Executive			
	Committee.			
	FPPE for Performance			
	The FPPE included criteria developed for evaluation of the			
	practitioners when issues affecting the provision of safe, high-			
	quality care were identified.			
	A timeframe for the FPPE was clearly documented.			
	There was evidence that the provider was educated about FPPE			
	prior to its initiation.			
	FPPE results were reported to the medical staff's Executive Committee.			
	Privileges and Scopes of Practice			
	The Service Chief, Credentialing Board, and/or medical staff's			
	Executive Committee list documents reviewed and the rationale for			
	conclusions reached for granting licensed independent practitioner			
	privileges.			
	Privileges granted to providers were setting, service, and provider			
	specific.			
	The determination to continue current privileges was based in part			
	on results of Ongoing Professional Practice Evaluation activities.			
	Table 6. C&P			

¹⁶ VHA Handbook 1100.19.

All CBOCs were compliant with the review areas; therefore, we made no recommendations.

EOC and Emergency Management

EOC

To evaluate the EOC, we inspected patient care areas for cleanliness, safety, infection control, and general maintenance. We reviewed relevant documents and interviewed key employees and managers. Table 7 shows the areas reviewed for this topic. The CBOCs identified as noncompliant needed improvement. Details regarding the findings follow the table.

NC	Areas Reviewed			
	The CBOC was American Disabilities Act-compliant, including:			
	parking, ramps, door widths, door hardware, restrooms, counters.			
	The CBOC was well maintained (e.g., ceiling tiles clean and in good			
	repair, walls without holes, etc.).			
	The CBOC was clean (walls, floors, and equipment are clean).			
	Material safety data sheets were readily available to staff.			
	The patient care area was safe.			
	Access to fire alarms and fire extinguishers was unobstructed.			
	Fire extinguishers were visually inspected monthly.			
	Exit signs were visible from any direction.			
	There was evidence of fire drills occurring at least annually.			
	Fire extinguishers were easily identifiable.			
	There was evidence of an annual fire and safety inspection.			
	There was an alarm system or panic button installed in high-risk			
	areas as identified by the vulnerability risk assessment.			
	The CBOC had a process to identify expired medications.			
	Medications were secured from unauthorized access.			
	Privacy was maintained.			
Bangor	Patients' PII was secured and protected.			
	Laboratory specimens were transported securely to prevent			
	unauthorized access.			
	Staff used two patient identifiers for blood drawing procedures.			
Bangor	IT security rules were adhered to.			
	There was alcohol hand wash or a soap dispenser and sink available			
	in each examination room.			
	Sharps containers were less than 3/4 full.			
	Safety needle devices were available for staff use (e.g., lancets,			
	injection needles, phlebotomy needles)			
Bangor	The CBOC was included in facility-wide EOC activities.			
Calais				
	Table 7. EOC			

<u>PII</u>. VHA requires that patients' PII is secured.¹⁷ At the Bangor CBOC, we found that two staff members did not secure their offices after regular working hours, and contracted non-VA employees could potentially have access to patient information. In another office, PII was left unattended in a folder on top of a desk.

IT Closet Security. According to VA, an access log must be maintained that includes the name and organization of the person visiting, signature of the visitor, form of identification, date of access, time of entry and departure, purpose of visit, and name and organization of person visited.¹⁸ At the Bangor CBOC, we found no evidence that a visitor access log to this area was maintained.

<u>Facility-Wide EOC Activities</u>. EOC rounds were regularly performed at the Bangor and Calais CBOCs, and appropriate corrective actions were taken. However, deficiencies and corrective actions were not tracked and trended by the EOC Committee.

Recommendations

- 3. We recommended that patients' PII is protected and secured at the Bangor CBOC.
- **4.** We recommended that the Chief of OI&T evaluates security of the IT closet and implements required measures at the Bangor CBOC.
- **5.** We recommended that all identified EOC deficiencies and corrective actions at the Bangor and Calais CBOCs are tracked and trended by the EOC Committee.

Emergency Management

VHA policy requires each CBOC to have a local policy or standard operating procedure defining how medical and MH emergencies are handled. Table 8 shows the areas reviewed for this topic.

NC	Areas Reviewed		
	There was a local medical emergency management plan for this		
	CBOC.		
	The staff articulated the procedural steps of the medical emergency		
	plan.		
	The CBOC had an automated external defibrillator onsite for cardiac		
	emergencies.		
	There was a local MH emergency management plan for this CBOC.		
	The staff articulated the procedural steps of the MH emergency plan.		
	Table 8. Emergency Management		

All CBOCs were compliant with the review areas; therefore, we made no recommendations.

¹⁷ VHA Handbook 1605.1, Privacy and Release of Information, May 17, 2006

¹⁸ VHA Handbook 6500

¹⁹ VHA Handbook 1006.1.

VISN 1 Director Comments

Department of Veterans Affairs

Memorandum

Date: April 26, 2013

From: Director, VISN 1 (10N1)

Subject: CBOC Reviews at VA Maine HCS

To: Director, Bedford Regional Office of Healthcare Inspections

(54BN)

Acting Director, Management Review Service (VHA 10AR

MRS OIG CAP CBOC

I have reviewed and concur with the action plans regarding

the VA Maine Healthcare System CBOC Report.

(original signed by:)

Michael Mayo-Smith, MD, MPH

Network Director

VA Maine HCS Director Comments

Department of Veterans Affairs

Memorandum

Date: April 25, 2013

From: Center Director (402/00), VA Maine HCS, Augusta, Maine

Subject: CBOC Reviews at VA Maine HCS

To: Network Director, VISN 1 (10N1)

- 1. We concur with the findings and recommendations presented in the VA Maine Healthcare System OIG Community Based Outpatient Clinic Review Draft Report. Comments to the report on the following pages comprise a brief implementation plan and target completion dates for each recommendation.
- 2. The organization benefited from the thorough review of the operations, systems, and processes, as well as from the inherent helpful, consultative nature of the team members' interaction with staff.
- 3. The goal to provide excellent quality of healthcare for the Veterans of Maine is, of course, always in our sights as we dedicate our efforts and resources every day.
- 4. Questions or further comments regarding this response can be directed to me with the anticipation of a complete and timely reply. Thank you.

RYAN S. LILLY

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

1. We recommended that a process is established to ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the allotted timeframe and that notification is documented in the EHR.

Concur

Target date for completion: April 4, 2013

All Primary Care providers and nurses were re-educated on April 4, 2013 at an "All Staff Meeting" of the note titles specifically developed for reporting normal cervical cancer results. Primary Care leadership requested that all providers to start using the note titles immediately to ensure tracking and timeliness of reporting normal results. The Women's Clinic will monitor compliance monthly.

2. We recommended that managers ensure that patients with normal cervical cancer screening results are notified of results within the defined timeframe and that notification is documented in the EHR.

Concur

Target date for completion: April 4, 2013

All Primary Care providers and nurses were re-educated on April 4, 2013 at an "All Staff Meeting" of the note titles specifically developed for reporting normal cervical cancer results. Primary Care leadership requested that all providers to start using the note titles immediately to ensure tracking and timeliness of reporting normal results. The Women's Clinic will monitor compliance monthly.

3. We recommended that patients' PII is protected and secured at the Bangor CBOC.

Concur

Target date for completion: April 19, 2013

Service Line Leadership reviewed the Privacy Policy Circular 00-12-31 with CBOC staff members specific to their expectations of security when office(s) are left unattended during and after normal business hours related to the security of patient health information. The Bangor Clinic Manager will perform monthly checks and report findings of non-compliance to appropriate Service Chief and Quality Manager for follow up.

4. We recommended that the Chief of OI&T evaluates security of the IT closet and implements required measures at the Bangor CBOC.

Concur

Target date for completion: August 2, 2013

Chief of OI&T will implement a visitor log in the Bangor CBOC by May 3, 2013. Full implementation will take longer as reflected in the completion date. A new circular and updated OI&T Standard Operation Procedure (SOP) will be published. OI&T staff will be trained during staff meetings of the change of procedure. Other staff that needs access to OI&T secure space will be required to sign new Memorandum of Understanding delineating responsibilities.

5. We recommended that all identified EOC deficiencies and corrective actions at the Bangor and Calais CBOCs are tracked and trended by the EOC Committee.

Concur

Target date for completion: March 25, 2013

A data base program has been created to track Environment of Care deficiencies and corrective actions identified during Environment of Care rounds in all Community Based Outpatient Clinics (CBOC). The data elements include name of CBOC, date of inspection, deficiency, corrective action, who is responsible, and date of resolution.

OIG Contact and Staff Acknowledgments

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U.S. Senate: Susan Collins, Angus King, Jr.

U.S. House of Representatives: Michael Michaud, Chellie Pingree

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